

REMARKS/ARGUMENTS

Claims 15-24 are currently pending. Claims 25 – 28 have been restricted. Claim 15 has been amended to more distinctly define the patentable subject matter. Applicants confirm election of claims of group 1, claims 15-24. Reconsideration of the rejections is requested.

Rejections Under 35 U.S.C. § 112

The examiner has rejected claims 15-24 as being indefinite, as claimed language "residue of amino acid" is not understood. The rejection is improper as this phrase is not present in claim 15. Withdrawal of the rejection is respectfully requested.

The examiner has rejected claims 15-24 under 35 USC §112 first paragraph, alleging that the specification does not reasonably provide enablement for treating a proliferative disease in a mammal or human. The rejection is respectfully traversed.

It is well established that if *in vitro* tests correlate to a claimed method of invention, it constitutes a working example sufficient to provide enablement of the claims. See, e.g., MPEP 2164.02. This is particularly the case in instances where the state of the art recognizes such a correlation. In the present case, the compounds of the invention were shown to have activity in binding the BIR3 peptide binding pocket. Such activity has been shown to have a correlation to promoting apoptosis, which in turn has been shown to be a therapeutic method of treating proliferative disease. See, e.g., Kipp et al, "Molecular Targeting of Inhibitor of Apoptosis Proteins Based on Small Molecule Mimics of Natural Binding Partners," *Biochemistry*, Vol. 41(23), pp 7344-7349 (2002); and Arnt et al., "Synthetic Smac/DIABLO peptides enhance the effects of chemotherapeutic agents by binding XIAP and cIAP1 *In Situ*," *Journal of Biological Chemistry*, Vol. 277 (46), pp. 44236-44243 (2002); both cited in the present IDS. There is therefore a clear corollary recognized in the art between the activity demonstrated in the specification and the resulting potential as a therapeutic against proliferative disease. Withdrawal and reconsideration of the rejection are respectfully requested.

The examiner has also rejected claims 15-24 under 35 U.S.C §112 first paragraph, as failing to comply with the written description requirement. In particular the examiner states, "if a biomolecule is described only by a functional characteristic without any disclosed correlation between function and structure of the sequence, it is 'not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence'." (Page 12 of the Office Action).

The rejection is traversed as it is improper. Applicants clearly recite structural formula I in claim 15 and in the specification. The rejection is improper because the

structure is definite and is described in the specification. The examiner even acknowledges that applicants have adequately described formulas I and II in the specification, but notes that there is insufficient description of "chemical modifications for membranes transport that would allow one of skill in the art to practice the invention as claimed." It is not required under 35 U.S.C. §112 however, to describe such chemical modifications beyond what is described in the present specification.

The purpose of the written description requirement is not that an applicant need to describe exactly the subject matter claimed, but the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. See, e.g., *In Re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). In the present case, it is acknowledged by applicants on page 7 of the application that, "substituents that facilitate transport of the molecule across a cell membrane are known to those of skill in the medicinal chemistry art." It is therefore not necessary to describe the substituents in detail; as they are merely state of the art which is known and may be used to practice the invention. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §102

Anticipation under 35 U.S.C §102 requires each and every limitation of the claim to be disclosed in a single prior art reference, either expressly or inherently. The anticipating reference must disclose the elements in the arrangement called for by the claim. If any limitation of the claim is missing, the reference does not anticipate.

Reconsideration is requested of the rejection of claims 15-24 as anticipated by U.S. Patent Publication No. 2005/0101538 to Rapin et al. Claim 15 has been amended to indicate that R_8 is $NR_{12}R_{13}$. Each of claims 16 through 24 depend on claim 15 either directly or indirectly. Claims 15-24 as presently defined are therefore not anticipated by Rapin. Withdrawal of the rejection is requested.


Double Patenting Rejection

Applicants acknowledge the provisional rejection based upon of nonstatutory obviousness-type double patenting. Applicants also acknowledge that if all other rejections are traversed, this rejection should be withdrawn, as the present application has an earlier filing date than U.S. application No. 11/203,370; see, e.g., MPEP 804. Accordingly, such action is respectfully requested.

The application is considered to be in condition for allowance and such action is solicited.

Respectfully submitted,

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